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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,400	06/20/2001	Dennis Murphy	DIVER1120-4	4902

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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/886,400

Applicant(s)

MURPHY ET AL.

Examiner

Delia M. Ramirez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) 1-23, 36-63, 65-85 and 88-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-35, 64, 86 and 87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Claims 1-92 are pending.

Applicant's election with traverse of Group II, claims 24-35, 64, 86-87 drawn to the polypeptide of SEQ ID NO: 4 and a preparation comprising said polypeptide, in Paper No. 9, filed on 3/29/2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-23, 36-63, 65-85, 88-92 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Inventorship

In view of the papers filed on 3/18/2002, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of inventors Jay M. Short and Eric J. Mathur.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

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Specification

1. The use of the trademarks has been noted in this application. See for example, "STRATAGENE", "BECKMAN", etc. in pages 71-72. They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "*Thermococcus alcaliphilus* enzymes having α -galactosidase activity and methods of use thereof".

Priority

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 09/619,032 filed on 7/19/2000, US application No. 09/407,806 filed on 9/28/1999, and US application No. 08/613,220 filed on 3/8/1996.

Drawings

4. The drawings have been reviewed and are objected under 37 CFR 1.84 or 1.152. See attached Notice of Draftsperson's Patent Drawing Review. Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in

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ABANDONMENT of the application. In addition, if amendments to the specification are needed due to drawing corrections, Applicant is requested to submit such amendments while the case is being prosecuted to expedite the processing of the application.

Claim Objections

5. Claims 24-34, 64 and 86-87 objected to because they depend on a non-elected claims. It is suggested that Applicants include the limitations of the non-elected claims in the instant claims. For examination purposes, the claims will be interpreted as having the limitations of the non-elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 24-35, 64 and 86-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claims 24 and 35 are indefinite in the recitation of "substantially identical" for the following reasons. While the term "substantially identical" is defined in the specification (page 9, lines 10-17) as meaning "at least 50% sequence identity", said term is also defined within the context of polypeptides, as "having one or more conservative or non-conservative amino acid substitutions, deletions, or insertions" (page 9, lines 19-23). For examination purposes, the term

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"substantially identical" will be interpreted as "at least 50% sequence identity". Correction is required.

8. Claims 24-35, 64, and 86-87 is indefinite in the recitation of "polypeptide of claims 22 or 23" or "polypeptide of claims 17 or 25" or "polypeptide of claim 1" as it is confusing since claims 1, 17, 22, and 23 recite "polynucleotides". For examination purposes, the claims have been interpreted as being directed to the polypeptides encoded by the polynucleotides of claims 1, 17, 22, or 23.

9. Claims 25-34 are indefinite in the recitation of "#% homology" as it is unclear which polypeptide property, such as function, sequence, etc., is used to determine "homology". It is suggested that the term "#% homology" be replaced with "#% sequence homology". Correction is required. For examination purposes, the term "#% homology" will be interpreted as "#% sequence homology".

10. Claims 25-28, 30, 32-34 (claims 86-87 dependent thereon) are indefinite in the recitation of "at least about" because it renders the claims vague and confusing. The use of this language is contradictory because the term "about" can be interpreted as "less than" whereas the term "at least" is synonym of "no less than". It is suggested that Applicants delete the term "about". Correction is required. For examination purposes, the term "at least about" will be interpreted as "at least".

11. Claim 35 is indefinite in the recitation of "polypeptide having a sequence as set forth in SEQ ID NO: 4 and sequences substantially identical thereto" as it is unclear how a polypeptide can have more than one sequence. It is suggested that the term "and" be replaced with "or".

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Correction is required. For examination purposes, the term "and sequences substantially identical thereto" will be interpreted as "or a sequence at least 50% identical thereto".

12. Claim 64 is indefinite in the recitation of "which is stable to heat, is heat resistant andtemperatures of from about 60 degrees to" for the following reasons. The terms "stable to heat" and "heat resistant" are relative terms not defined by the claim, the specification does not provide a standard for ascertain the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For examination purposes, the terms "stable to heat" and "heat resistant" will be given no patentable weight as they are undefined. The term "temperatures of from about" is redundant and confusing. It is suggested that the term "temperatures of from about" be replaced with more clear and unambiguous language, such as "temperatures of 60 degrees to". Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 24-35 and 86-87 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 24-34 and 86-87 are directed to genera of polypeptides of any function wherein the polypeptides (1) comprise at least 10 consecutive amino acids of the polypeptide of SEQ ID

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NO: 4 or (2) have an amino acid sequence which is at least 50%-95% identical to that of SEQ ID NO: 4 or a polypeptide comprising 10 consecutive amino acids of SEQ ID NO: 4. The specification discloses the polynucleotide of SEQ ID NO: 3 and the corresponding polypeptide (SEQ ID NO: 4). According to the specification, the polypeptide of SEQ ID NO: 4 has α -galactosidase activity (pages 1-2). While Applicants have disclosed the function of the polypeptide of SEQ ID NO: 4, no disclosure has been made of the function of polypeptides comprising at least 10 consecutive amino acids of the polypeptide of SEQ ID NO: 4 or polypeptides having an amino acid sequence at least 50-95% identical to that of SEQ ID NO: 4. No information beyond the disclosure of SEQ ID NO: 4 and its function has been provided by Applicant which would indicate possession of the claimed genera of polypeptides. In addition no disclosure of the critical structural elements required for α -galactosidase activity, such as the catalytic domain, binding domain, etc. has been provided. No disclosure of which structural elements (1) a polynucleotide having at least 50% sequence identity to the polynucleotide of SEQ ID NO: 3 or (2) any of the variants of SEQ ID NO: 4 as encompassed by the claims, should have to display α -galactosidase activity. Furthermore, the specification is silent in regard to the enzyme's stability to heat and its ability to renature and regain activity after exposure to temperatures of 60 °C to 105 °C.

While one can argue that function can be inferred by sequence comparison with a known protein of known function, the state of the art teaches that small amino acid changes can drastically change a protein's function. The state of the art teaches that sequence comparison alone should not be used to determine a protein's function and that small amino acid changes can drastically change the function of a polypeptide. Bork (Genome Research, 10:348-400, 2000)

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teaches protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* where found to be hydroxylases once tested for activity. Broun et al. (Science 282:1315-1317, 1998) teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase. Many functionally unrelated polypeptides are encompassed within the scope of these claims. The specification only discloses a single species of the claimed genera which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the claimed genera. Thus, one skilled in the art cannot reasonably conclude that Applicant had possession of the claimed invention at the time the instant application was filed.

14. Claims 24-35, 64 and 86-87 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 4 or the polypeptide encoded by the polynucleotide of SEQ ID NO: 3, does not reasonably provide enablement for polypeptides (1) which comprise at least 10 consecutive amino acids of the polypeptide of SEQ ID NO: 4, (2) which have an amino acid sequence which is at least 50%-95% identical to that of SEQ ID NO: 4 or any polypeptide comprising 10 consecutive amino acids of SEQ ID NO: 4, or (3) having α -galactosidase activity which are encoded by a nucleic acid comprising a nucleotide sequence of at least 50% sequence identity to SEQ ID NO: 3 wherein the polypeptide is stable to heat, catalyses the hydrolysis of saccharides, and is able to regain activity after exposure to temperatures of 60 °C to 105 °C. The specification does not enable any person skilled in the art

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to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The scope of claims 24-35, 64 and 86-87 is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides encompassed by the claims. While Applicants have disclosed the function and structure of the polypeptide of SEQ ID NO: 4, no disclosure of the function of the polypeptides encompassed by claims has been provided. The specification does not provide any information as to which structural elements are related to α -galactosidase activity. In addition, there is no disclosure of which structural elements (1) a polynucleotide having at least 50% sequence identity to the polynucleotide of SEQ ID NO: 3 or (2) any of the variants of SEQ ID NO: 4 as encompassed by the claims, should have to display α -galactosidase activity. Furthermore, the specification is silent in regard to the enzyme's stability to heat and its ability to renature and regain activity after exposure to temperatures of 60 °C to 105 °C.

As indicated previously, the current state of the art indicates that small amino acid changes can drastically change the function of a polypeptide. See, for example, the teachings of Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) and Broun et al. (Science 282:1315-1317, 1998), already discussed. The amino acid sequence of the polypeptide

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determines its structural and functional properties, therefore, one of skill in the art would require some knowledge and guidance as to how structure is related to function in order to (1) determine the function of a polypeptide which comprise at least 10 consecutive amino acids of the polypeptide of SEQ ID NO: 4, or which have an amino acid sequence which is at least 50%-95% identical to that of SEQ ID NO: 4, or (2) isolate polypeptides having α -galactosidase activity which are encoded by a nucleic acid comprising a nucleotide sequence of at least 50% sequence identity to SEQ ID NO: 3 wherein the polypeptide is stable to heat, catalyses the hydrolysis of saccharides, and is able to regain activity after exposure to temperatures of 60 °C to 105 °C. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to maintain the desired function, the lack of information provided in regard to the enzyme's stability to heat, and the unpredictability of the prior art in regard to function based on homology, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to screen and isolate those polypeptides, as encompassed by the claim, with α -galactosidase activity, heat stable, capable of hydrolyzing saccharides, or able to renature and regain activity after exposure to temperatures of 60-105 °C. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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15. Claims 24-35 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwarabayasi et al. (PIR accession number E71144, August 14, 1998). Kwarabayasi et al. teaches a *Pyrococcus horikoshii* polypeptide which is 80% sequence identical to the polypeptide of SEQ ID NO: 4. Also, the polypeptide of Kwarabayasi et al. comprises several fragments of 10 or more consecutive amino acids which are 100% sequence identical to fragments of the polypeptide of SEQ ID NO: 4. In addition, the sequence identity was determined by a sequence comparison algorithm.

Claims 24-35 and 64 are directed to polypeptides having 50%-95% sequence homology to the polypeptide of SEQ ID NO: 4 or to a polypeptide comprising at least 10 amino acids of the polypeptide of SEQ ID NO: 4. *Pyrococcus horikoshii* is a thermophile, therefore a protein derived from this organism would be inherently thermostable. Since the office does not have a laboratory to test the polypeptide of the instant reference, it is applicant's burden to show that the polypeptide of Kwarabayasi et al. is not thermostable. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980). Therefore, the polypeptide of Kwarabayasi et al. anticipates the claims as written.

16. It should be noted that Applicant's priority claim to non-provisional US application No. 09/619,032, 09/407,806 and 08/613,220 is not applicable to the instant claims since SEQ ID NO: 4 has not been disclosed in the parent applications.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 86-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawarabayasi et al. (PIR accession number E71144, August 14, 1998). The teachings of Kawarabayasi et al. have been discussed above. Kawarabayasi et al. does not teach a liquid or dry preparation containing the polypeptide.

Claims 86-87 are directed to dry or liquid enzyme preparations comprising a polypeptide having at least 50% sequence homology to the polypeptide of SEQ ID NO: 4 or to a polypeptide comprising at least 10 consecutive amino acids of SEQ ID NO: 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a dry or liquid preparation with the polypeptide of Kawarabayasi et al. A person of ordinary skill in the art is motivated to make dry or liquid preparations of a protein

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since one would prefer a dry preparation for storage and a liquid preparation for immediate use. One of ordinary skill in the art has a reasonable expectation of success at making a liquid or dry enzyme preparation because (1) enzymes are always produced in the liquid state and (2) enzyme drying methods are well known in the art (i.e. freeze-drying). Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 24-35, 64 and 86-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 15 of U.S. Patent No. 5,958,751. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Claims 1 and 15 of U. S. Patent No. 5,958,751 are directed to a polypeptide having a sequence which is 84 % identical to SEQ ID NO: 4 of the instant application. In addition, the polypeptide of U. S. Patent No. 5,958,751 comprises several

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fragments of at least 10 consecutive amino acids which are identical to those of SEQ ID NO: 4 of the instant application. Claims 24-35 and 64 of the instant application are directed to polypeptides having 50%-95% sequence homology to (1) the polypeptide of SEQ ID NO: 4, (2) to a polypeptide comprising at least 10 amino acids of the polypeptide of SEQ ID NO: 4, or (3) the polypeptide encoded by a polynucleotide of at least 50% sequence identity to SEQ ID NO: 3. Claims 86-87 of the instant application are directed to dry or liquid preparations comprising said polypeptides. Since dry or liquid preparations comprising polypeptides are obvious inventions as discussed previously, the claims of the instant application and those of U.S. Patent No. 5,958,751 are not patentably distinct.

22. Claims 24-35, 64 and 86-87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10 and 11 of copending Application No. 09/407,806. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Claims 10 and 11 of copending Application No. 09/407,806 are directed to a polypeptide comprising an amino acid sequence which is 84% identical to SEQ ID NO: 4 of the instant application. In addition, the polypeptide of copending Application No. 09/407,806 comprises several fragments of at least 10 consecutive amino acids which are identical to those of SEQ ID NO: 4 of the instant application. Claims 24-35 and 64 of the instant application are directed to polypeptides having 50%-95% sequence homology to (1) the polypeptide of SEQ ID NO: 4, (2) to a polypeptide comprising at least 10 amino acids of the polypeptide of SEQ ID NO: 4, or (3) the polypeptide encoded by a polynucleotide of at least 50% sequence identity to SEQ ID NO: 3. Claims 86-87 of the instant application are directed to dry or liquid preparations comprising said polypeptides. Since dry or

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liquid preparations comprising polypeptides are obvious inventions as discussed previously, the claims of the instant application and those of copending Application No. 09/407,806 are not patentably distinct.

23. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. It is noted that Applicant's application Serial No. 10/112,357, 10/112,418, 10/112,442, 10/114,083, 10/114,403, 10/116,581, 10/112,331, 10/116,606, 10/112,377 disclose a polypeptide having 100% sequence homology to the polypeptide of SEQ ID NO: 4. Since these applications are not available to the examiner at this time, no determination has been made as to whether or not a double patenting rejection over the claims from these applications should be applied to the claims of the instant application. If, upon availability of the above application to the Examiner, it is determined that there are conflicting claims between application Serial No. 10/112,357, 10/112,418, 10/112,442, 10/114,083, 10/114,403, 10/116,581, 10/112,331, 10/116,606, 10/112,377 and the instant application, double patenting will not be considered as new ground(s) of rejection.

25. Applicants are advised that should claim 25 be found allowable, claim 24 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claim 25 is merely reciting the definition of "substantially identical" as interpreted (see interpretation of claim 24 above) from the specification in the claim.

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Conclusion

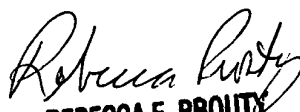
26. No claim is in condition for allowance.

27. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

28. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP-1800
1600

Delia M. Ramirez, Ph.D.
Patent Examiner
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